

To: All Kentucky Medicaid Prescribers and Pharmacy Providers
From: Kentucky Medicaid Program
CC:
Date: September 10, 2008
Subject: Tamper Resistant Prescription Pads Requirement Update

EFFECTIVE October 1, 2008

Dear *KyHealth Choices* Provider:

This letter is an update to a previous mailing dated March 20, 2008 and contains important information regarding compliance with the federally mandated Medicaid Tamper Resistant Requirements.

As of October 1, 2008, the second phase of the CMS tamper-resistant prescription law will take effect, and will require that all handwritten and/or computer generated (by an EMR or ePrescribing applications) printed prescriptions for fee-for-service Medicaid patients be fully compliant with federal and/or state guidance for prescription tamper resistance. Please note that these requirements do not apply to commercial Medicaid programs, such as the Passport Health Plan.

Review of CMS Requirements

Currently, a handwritten or computer generated prescription must contain a feature in at least one of the following three characteristic categories to be compliant. However, by October 1, 2008 handwritten or printed prescriptions must contain a feature within **all three** categories. No one feature may be counted twice.

The Three Categories:

1. Copy Resistance: One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form.
2. Erasure/Modification Resistance: One or more industry-recognized feature designed to prevent the erasure or modification of information written on the prescription by the prescriber.
3. Counterfeit Resistance: One or more industry-recognized feature designed to prevent the use of counterfeit prescription forms.

For more information about the Federal tamper resistant requirements, please visit the following website: www.cms.hhs.gov/deficitreductionact/20_govinfo.asp

Also, please see CMS clarification on prescriptions printed from an EMR or an ePrescribing application. These paper prescriptions must contain a feature from all three requirements to be in compliance with this mandate.

- **Prior guidance for printed prescriptions generated from EMRs or ePrescribing applications stated that special copy resistant paper would likely be required for printed prescriptions to be in compliance as of October 1, 2008. CMS has clarified this statement, and is now stating that while special paper may be used to achieve copy resistance – it is not necessary. EMR or ePrescribing generated prescriptions may be printed on plain paper and be fully compliant with all three categories of tamper resistance provided they contain at least one feature from each of the three categories detailed below.**

Revised Kentucky Requirements

The Department has undertaken a rigorous effort to meet with all stakeholders involved in the prescription process to identify opportunities to improve communication of this requirement and look for opportunities to lessen the impact on all providers. The Department also recognizes that there is much confusion regarding these requirements.

The Department is making the following changes to the program:

1. The use of prescription pads in compliance with the controlled substances requirements outlined in 902 KAR 55:105 is the preferred method for meeting the Kentucky standard for this federally required program;

OR

2. The use of prescription pads with features outlined in the attachment to this letter are examples of ‘best practices’ utilized across the country to meet the federal requirements. All of these practices are acceptable to the Center for Medicare and Medicaid Services (CMS) and to the Commonwealth of Kentucky, provided at least one feature from category one and three is present on every hand-written or computer printed prescription AND one feature from both sub-categories in category two is present on every hand-written or computer printed prescription. Please note that no feature may be used twice.

It should be noted all controlled substances are required to be written on a controlled substance prescription pad in accordance with 902 KAR 55:105.

As a reminder, in an emergency situation, prescriptions written on non-tamper resistant pads will be permitted to be billed to Medicaid as long as the prescriber provides a verbal, faxed,

electronic or compliant written prescription within 72 hours after the date on which the prescription was filled. It is the responsibility of the pharmacy to obtain the compliant written prescription from the prescriber in order to ensure payment from Medicaid if that is the chosen method for meeting the requirement.

We appreciate your continued compliance and cooperation with these federal regulations and thank you in advance for your efforts.

Summary Of Features In Compliance With The CMS Guidelines And Acceptable To The Commonwealth Of Kentucky Medicaid Program.

<u>Category 1 – Copy Resistance:</u> One or more industry recognized features designed to prevent unauthorized copying of a completed or blank prescription form.	
Feature	Description
“Void,” “Illegal,” or “Copy” pantograph <u>with or without</u> Reverse “Rx”	<p>The word “Void,” “Illegal,” or “Copy” appears when the prescription is photocopied. The pantograph should be configured so as not to obscure the security feature description contained on the prescription, the patient and prescriber demographics, or the medication and directions.</p> <p>Some pantographs can be problematic because when the prescription is copied, the resulting “void” or other wording that appears makes the underlying prescription difficult to read. This type of pantograph should be avoided. We suggest that you ask your pad vendor about hollow “VOID” pantograph lettering which is less likely to obscure the prescription information.</p> <p>The Reverse Rx disappears when copied at a light setting – thus making the pantograph more effective in copy resistance. The pantograph may be used with a reverse Rx, but reverse Rx is not effective as a feature by itself.</p>
Micro printing – To be effective, this feature must be printed in 0.5 font or less making it illegible to the pharmacist when copied	Very small font which is legible (readable) when viewed at 5x magnification or greater, and illegible when copied.
Thermochromic ink	Ink changes color with temperature change.
Coin-reactive ink	Ink changes color when rubbed by a coin.
<u>Watermarking</u>	
Security back print (artificial watermark)	Printed on the back of prescription form. The most popular wording for the security back print is

Digital watermarks	“Security Prescription” or the security back print can include the states name. Can only be seen when viewed at an angle.
Watermarking on special paper	Weak digital watermarks cannot be read if copied and strong digital watermarks provide digital rights management/“proof” of origin when copied. Special paper contains a watermark that can be seen when backlit.

Category 2 – Erasure / Modification Resistance: One or more industry-recognized features designed to prevent the erasure or modification of information written / printed on the prescription by the prescriber. (NOTE: THERE ARE TWO SUB-CATEGORIES)

<u>Sub-Category 2: Features to Prevent Erasure</u>	Description
An erasure revealing background (erasure resistance)	Background that consists of a solid color or consistent pattern that has been printed onto the paper. This will inhibit a forger from physically erasing written or printed information on a prescription form. If someone tries to erase, the consistent background color will look altered and show the color of the underlying paper.
Toner Receptor Coating / Toner Lock or Color Lock paper (erasure resistance for computer generated prescriptions <u>printed with a laser printer</u>) OR Chemically reactive paper (erasure resistance for hand written prescriptions)	Special printer paper that establishes a strong bond between laser-printed text and paper, making erasure obvious. Note – this is NOT necessary for inkjet printers – as the ink from inkjet printers is absorbed into normal “bond” paper. If exposed to chemical solvents, oxidants, acids, or alkalis that can be used to alter the prescription, the chemically reactive paper will react and leave a mark visible to the pharmacist.
<u>Sub-Category 2: Features to Prevent Modification</u>	Description
Quantity check off boxes and refill indicator (circle or check number of refills or “NR)	In addition to the written quantity on the prescription, quantities are indicated in ranges. It is recommended that ranges be 25’s with the highest being “151 and over”. The range box corresponding to the quantity prescribed MUST be

	checked for the prescription to be valid. The refill indicator indicates the number of refills on the prescription. Refill numbers must be used to be a valid prescription.
Pre-printed language on prescription paper Example: “Rx is void if more than XXX Rx’s on paper”	Reduces ability to add medications to the prescription. Line must be completed for this feature to be valid. Computer printer paper can accommodate this feature by printing, “This space intentionally left blank” in an empty space or quadrant.
Quantity and Refill Border and Fill (this is the recommended for computer generated prescriptions)	Quantities and refill # are surrounded by special characters such as an asterisks to prevent modification, e.g. QTY **50** Value may also be expressed as text, e.g. (FIFTY), (optional).

Category 3 – Counterfeit Resistance: One or more industry-recognized feature designed to prevent the use of counterfeit prescription forms.

Feature	Description
Security features and descriptions listed on prescriptions – this feature is <u>strongly</u> recommended on all prescriptions	Complete list of the security features on the prescription paper for compliance purposes. This is strongly recommended to aid pharmacists in identification of features implemented on prescription.
Thermochromic ink	Ink changes color with temperature change.
Security Thread	Metal or plastic security threads embedded in paper as used in currency.